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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/672,142 | 09/26/2003 | David J. Yang | UTSC:664USC2 | 6122 |
| 32425 | 7590 | 02/21/2006 | EXAMINER | |
| FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701 | | | JONES, DAMERON LEVEST | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/672,142 | Applicant(s) YANG ET AL. | |
| | Examiner D. L. Jones | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-84 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 54-84 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/28/05 wherein claims 1-53 are canceled and claim 84 is added. In addition, the Examiner acknowledges the acceptable RCE filed 11/28/05.

Note: Claims 54-84 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments filed 11/28/05 to the rejection of claims 54-83 made by the Examiner under 35 USC 103 and/or double patenting have been fully considered and deemed non-persuasive for the reasons set forth below.

Double Patenting Rejections

I. The provisional rejection of claims 54-64, and 67-84 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 32, and 38-42 of copending application number 10/732,919 is MAINTAINED for reason of record in the office action mailed 3/8/05.

II. The provisional rejection of claims 54-59, 64, and 67-79 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-41 and 60 of copending application number 09/599,152 is MAINTAINED for reason of record in the office action mailed 3/8/05.

III. The provisional rejection of claims 56-59 and 63-66 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 38-41 of copending application number 10/672,763 is MAINTAINED for reason of record in the office action mailed 3/8/05.

IV. The provisional rejection of claims 56, 57, and 63-66 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 27, 28, and 34-37 of copending application number 10/703,405 is MAINTAINED for reason of record in the office action mailed 3/8/05.

Note: It is duly noted that Applicant intends to address the double patenting rejections at which time the claims are indicated as patentable over the prior art.

103 Rejection

The rejection of claims 54-68, 70, and 80 under 35 USC 103(a) as being unpatentable over Dean et al (US Patent No. 5,716,596) is MAINTAINED for reasons of record in the office action mailed 8/24/05 and those set forth below.

Applicant asserts that the instant invention is distinguished over the Dean et al because the cited prior art neither teaches nor suggests that (1) the conjugates are capable of being taken into cells and (2) the radionuclide is covalently linked to the peptide in the Dean et al conjugate whereas the radionuclide is covalently linked to the bisaminoethanethiol moiety in the instant invention.

Applicant's arguments are found non-persuasive because a recitation that an element is capable of being taken up into the target cells is not a positive limitation, but only requires the ability to so perform that function. Thus, such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138).

Furthermore, it should be noted that if you have the same components present in a

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composition, then their properties would be expected to be the same. Hence, a skilled practitioner in the art would recognize that both Applicant's composition and that of Dean et al may be taken into the cells. Also, it is noted that in column 9, line 58, through column 10, lines 16, it is disclosed that the imaging reagents of Dean et al may be used for visualizing organs and that in most instances, a sufficient amount of the reagent accumulates in the area to be imaged. Thus, a skilled practitioner in the art would recognize that the composition is internalized by the cells since it is not an outline of the organ that is generated, but accumulation of the reagent in the area of interest that is imaged.

In response to Applicant's comment (2) above, it is noted that Applicant's claim 54, section (b), reads 'a composition comprising a radionuclide-labeled bis-aminoethanethiol (BAT) targeting ligand conjugate'. Now, since column 5, line 53, through column 6, line 14, especially, line 53, disclose 'the bisamino bisthiol Tc-99m binding moiety', a skilled practitioner in the art would recognize that the technetium-99m radionuclide binds to the BAT moiety and the Tc-99m bisamino bisthiol binding moiety conjugates with the peptide to generate the radiolabeled peptide complex (see column 5, lines 48-53). Also, in column 9, lines 14-17, it is disclosed that that one advantage of the instant invention is that the thioether linkage is stable under the conditions of Tc-99m conjugation to the covalently linked Tc-99m binding moiety. Hence, it is the Examiner's position that both Applicant and Dean et al disclose compositions wherein the radionuclide is covalently linked to the bisaminoethanethiol moiety.

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COMMENTS/NOTES

3. It is once again noted that the cited prior art neither anticipates nor renders obvious the additional claim limitations of claims 69, 71-79, and 81-84 as set forth in the instant invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
Art Unit 1618

February 13, 2006